

## REMARKS

The patent application filed herewith is a continuation of U.S. Application No. 10/423,232, filed April 25, 2003.

The present invention relates to methods of treating patients suffering from a disease, disorder or condition characterized by a defect of a blood vessel.

Claims 55-77 are currently pending in the present application following entry of the present Preliminary Amendment. Claims 1-54 have been deleted herein. Support for the addition of new claims 55-77 is found in the specification as filed and as set forth below. Therefore, these new claims do not constitute new matter.

### Amendments to the Specification

The specification has been amended herein to properly reflect the priority information of the present Application. In particular, page 1 of the specification has been amended to indicate that the present Application is a continuation of U.S. Application No. 10/423,232, filed April 25, 2003, which is a continuation of U.S. Application No. 08/913,918, filed December 8, 1997, which is a continuation of PCT Application No. PCT/US96/04407, filed March 28, 1996, which is a continuation-in-part of U.S. Application No. 08/412,066, filed March 28, 1995 (issued on February 10, 1998 as U.S. Patent No. 5,716,616), and which claims priority to U.S. Provisional Application No. 60/006,627, filed on November 13, 1995.

The specification has also been amended herein to properly add an abstract section to the application. Applicants respectfully point out that the present abstract is identical to the abstract filed in International Application No. PCT/US96/04407 and published on the face of International Publication Number WO 96/30031. Thus, the amendments to the specification do not add new matter.

### Support for new claims 55-77 found in the specification as filed

Support for claim 55, relating to generating a blood vessel in a mammal, is found throughout the specification. Specifically, in lines 8-10 on page 13, the specification discloses that isolated stromal cells can develop into a blood vessel. Further, beginning in line 30 on page 8, the specification discloses that isolated stromal cells, when administered to a mammal, can act as precursor cells which produce daughter cells that mature into differentiated cells. That is, the

cells of the present invention can differentiate and develop into, but not limited to, cells of the blood vessels.

Support for claim 56, relating to a disease, disorder, or condition characterized by a defect in a blood vessel, is found throughout the specification. Specifically, beginning on line 9 on page 6, the specification discloses that a disease, disorder or condition characterized by a defect in a blood vessel refers to a disease, disorder or conditions which can be caused by, but not limited to a genetic mutation in a gene that is expressed by a cell of the blood vessel such that one of the effects of such a mutation is manifested by abnormal structure and/or function of the blood vessel.

Support for claims relating to the different modes for administration of bone marrow stromal cells into a mammal is found throughout the specification. Specifically, support for systemic administration of the cells of the present invention is found in line 7 on page 13. Support for intravenous administration of the cells is found in line 10 on page 9. Support for the intraperitoneal administration of the cells is found in line 19 on page 27. Support for the intra-arterial administration of the cells is found in line 36-37 on page 8, wherein the specification teaches that the cells can be administered into the blood stream.

Support for claim 63, relating to repairing or regeneration a blood vessel in a mammal, is found throughout the specification. Specifically, in line 7-9 on page 11, the specification teaches treating a disease with supplementing, augmenting and/or replacing defective cells with cells of the present invention. Therefore, one skilled in the art, when armed with the present specification would understand that the cells of the present invention could be used to repair or regenerate a blood vessel in a mammal.

Support for claim 70, relating to a method of treating a disease, disorder or condition characterized by a defect in a blood vessel in a mammal, is found beginning in line 20 on page 3, wherein the specification teaches amongst other things a method of treating a patient who is suffering from a disease by administering the cells of the present invention to the patient.

Support for claim 71, relating to peripheral vascular disease is found throughout the specification. As discussed elsewhere herein, the specification supports repair and/or treatment of defects of a blood vessel. Applicants point out that it is known in the art that peripheral vascular disease can be caused by a build-up of plaque in the arteries outside heart and brain which can result in the reduced flow of blood to peripheral areas such as, but not limited to

legs, arms, kidneys and neck. In addition, peripheral vascular disease can also be caused by structural changes or defects in the blood vessel. Accordingly, Applicants respectfully point out that the specification fully supports claim 71 for reciting peripheral vascular disease.

Applicants respectfully submit that new claims 55-77 are supported by the as-filed specification and therefore new claims 55-77 do not constitute new matter.

Summary

Applicants respectfully submit that claims 55-77, following entry of the present Amendment, are in condition for allowance. Allowance of claims 55-77 is respectfully requested at the earliest possible date.

Respectfully submitted,

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(Date)

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